

REMARKS

Claims 20-52 are pending. Claims 22-25, 27-28, 30-46 and 48-52 are withdrawn from consideration by the Office as being drawn to a non-elected invention. Claims 20, 21, 26, 29 and 47 are examined. Applicants voluntarily cancel claim 47. Claims 20-21, 26 and 29 are currently amended. Applicants amend claims 39-44 and request rejoinder, pending allowance of claim 20 (please see II below). Support for the amendments can be found at least at pages 5-23 and 27-53 of the specification. No new matter has been introduced.

I. Formal Matters

Applicants thank the Office for perfecting Applicants' claim to priority, acknowledging the Information Disclosure Statement submitted on September 15, 2003, and accepting the drawings as filed.

II. Claim 20 is Proper

At page 2 of the Office Action, claim 20 is objected to as allegedly containing non-elected sequences in view of Applicants' election of Group I, SEQ ID NOs:7, 18, 5, 2, 12, 4, 13, 14 and 16, without traverse.

Applicants' amended claims do not recite the non-elected species. In view of the above, withdrawal of the objection to claim 20 is kindly requested.

III. Claims 20, 21, 26, 29 and 47 Are Definite Under 35 U.S.C. §112

At page 2 of the Office Action, claims 20, 21, 26, 29 and 47 are rejected under U.S.C. §112, second paragraph, as allegedly being indefinite. The Examiner asserts that the meaning of the term "functional sequence" in claim 20 is indefinite since it is allegedly unclear if the sequence needs to have all or one of the functions of the sequences identified in the application.

Applicants disagree that the claims are indefinite. At least paragraphs 51, 54, 63, 72, Table 7 and Table 8 define a functional sequence as a sequence that, when present upstream of the minimal promoter, activates transcription.

In order to expedite prosecution and solely in order to better illustrate the commercial embodiments of the invention, Applicants amend claim 20 to include the recitation of “and activates transcription.”

Because the phrase “functional sequence” is clear, in the claims and the specification, withdrawal of the indefiniteness rejection is kindly requested.

IV. Claims 20, 21, 26, 29 and 47 Are Supported by The Specification

At page 3 of the Office Action, claims 20, 21, 26, 29 and 47 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description support in the specification. The Office asserts that the claims are directed to a synthetic promoter comprising a number of different elements, or functional versions of those elements having between 50% and 75% identity to the elements. The Examiner alleges that the claims read on a broad genus of promoters but states that there are no examples of promoters containing functional versions of the recited elements.

Applicants disagree with the Examiner. First, as can be seen from the Table 1, various domains are cloned in multiple copies in the front of the minimal promoter, P_{mec}.

TABLE 1¹

| Activating sequence (Each of these small sequences is present in the complete promoter) | GUS activity (X10 ³ pmol MU/min/mg protein ±SD) | Fold activation |
|---|--|-----------------|
| P _{mec} (-38 to +100) | 2.67 ± 0.18 | 1 |
| (TGACG) ₁₈ -P _{mec} : | 6.28 ± 0.56 | 2.35 |
| (CACAAAT) ₁₈ -P _{mec} | 20.29 ± 1.21 | 7.6 |
| (GTGGAAA) ₁₈ -P _{mec} | 13.48 ± 1.07 | 5.1 |
| (ACGT) ₁₈ -P _{mec} | 9.76 ± 0.61 | 3.7 |

¹ Sawant *et al.*, 2005, Journal of Experimental Botany, Vol, 56, pp.2345-2343.

| | | |
|--|-----------------|------|
| (GATA) ₁₈ -P _{mec} | 8.57 ± 0.48 | 3.2 |
| (ACGTAAGCGCTTACGT) ₁₈ -P _{mec} | 7.34 ± 0.51 | 2.7 |
| (AGAAAAGG) ₁₈ -P _{mec} | 12.36 ± 1.09 | 4.6 |
| (CGATCTGACCATCTCTAGATCG) ₁₈ -P _{mec} | 6.60 ± 0.46 | 2.5 |
| (-350 to -38 in single copy) – P _{mec} | 293.6 ± 28.62 | 110 |
| (-350 to -38 in three copies) – P _{mec} | 4014.0 ± 491.54 | 1503 |

The resultant promoter has each domain represented at a different position to SEQ ID NO.:1, *i.e.*, the original promoter. For example, in the original SEQ ID NO.:1, SEQ ID NO.:10 is present -195 upstream of the transcription start site. In the synthetic construct used in Table 1, where SEQ ID NO.:10 is repeated 18 times upstream of the P_{mec} and is therefore present at a different start site from -32 to -320, the promoter is significantly active in the plant cell. Similarly in another example from Table 1, *i.e.*, the last construct, use of the entire region spanning from -35 to -350 triples the activity of the synthetic promoter, but activity is enhanced 15 fold compared to the promoter of SEQ ID NO.:1. Table 1 provides exhaustive examples illustrating that multiple species have been reduced to practice by the Applicants. The specific examples demonstrate that when domains are shuffled to place sequences in different locations, the resultant promoters activate transcription. Thus, claims 20, 21, 26, 29 and 47 encompass promoters reduced to practice by the Applicants.

Secondly, the Applicants herewith provide a detailed analysis of SEQ ID NO.:2, using saturation mutagenesis. Declaration Under 37 C.F.R. § 1.132. As discussed in the Declaration, Applicants studied 39 mutations in SEQ ID NO.:2 for their effect on the gene expression in plant cells *in vivo*. Of the 39 mutations, 23 mutations (59%) significantly (more than 10%) decreased the gene expression while 11 mutations (28%) increased gene expression significantly. 13% did not show any significant effect on gene expression in plant cells. Applicants' results indicate that even with a 41% change in the SEQ ID NO.:2, Applicants obtain a synthetic promoter that activates transcription. Variants, which are functionally identical, are claimed in the present invention.

Accordingly, withdrawal of the rejection is kindly requested.

V. Double Patenting

At page 5 of the Office Action claim 20 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. patent number 6,639,065 (“the ‘065 patent”).

This application is a divisional of 09/263,692 (now the ‘065 patent) and was filed as the result of a Restriction Requirement issued in the ‘692 application. Accordingly, 35 U.S.C. 121 prevents the ‘065 patent from being used as a reference against the present application.

Accordingly, the rejection is legally improper and should be withdrawn.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/William J. Simmons/

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

William J. Simmons, Ph.D.
Registration No. 59,887

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: June 20, 2007